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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,905	07/24/2006	John Godber	99342.00061	2254
21832 7590 09/18/2009 MCCARTER & ENGLISH, LLP HARTFORD CITYPLACE I 185 ASYLUM STREET HARTFORD, CT 06103			EXAMINER RUMP, RICHARD M	
			ART UNIT 1793	PAPER NUMBER
			MAIL DATE 09/18/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,905

Applicant(s)

GODBER ET AL.

Examiner

Richard M. Rump

Art Unit

1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

Claims 1-5 are pending and presented for examination. Claims 12-23 were withdrawn as being drawn to a non-elected group. Claims 6-8 and 24-33 stand cancelled. Claim 1 stands amended via amendment dated 6 July 2009.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over C. Pontier, "About the Use of Stoichiometric Hydroxyapatite in Compression Incidence of Manufacturing Process on Compressibility" (Hereinafter referred to as Pontier -- Provided by Applicant).

Regarding claims 1-2, Pontier discloses a composition of a stoichiometric hydroxyapatite (HA) of the formula $(\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2)$. The average (d_{50}) particle size is between 185 and 225 microns (200 specifically which would meet ("at least 90% of the particles are larger than 10 microns" in this case 90% would be larger than 10 microns and 10% could obviously be smaller than 260)) (Table 1; paragraph 1 (right hand column)). The solid line on figure 4 (page 253) shows the particle size distribution curves. A solid line is shown that 90% of the particles are smaller than 260 microns and 90% are larger than 10. Furthermore it is apparent that at a minimal that the selected average can be determined from the particle size distribution and as such in event of

arguendo, a *prima facie* case of obviousness exists as this would overlap that which is instantly claimed (See MPEP 2144.05). Furthermore it would be obvious to a skilled artisan sieve the particles in any size.

Regarding claim 5, the specific surface area (BET) of the 200 micron batch is between 10 and 100 m²/g (table 2 – specifically 44.6+/-4.5 m²/g).

Regarding claim 11, given if x is set equal to 0 in the instant claim, the composition disclosed as stated above by Pontier would read upon that instantly claimed. It is stated in the abstract that the composition withstand great compressive loads.

Claims 1, 3-4 & 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh, *et al.*, A New Porous Hydroxyapatite Ceramic Prepared by Cold Isostatic Pressing and Sintering Syntehsized Flaky Powder”.

Regarding claims 1 & 3, Itoh discloses that the average HA particle size is 200 microns and the apparent porosity (density) is 0.7. It would be obvious to one of skill in the art that 90% of the particles would be greater than 10 and 90% less than 260 (15 microns; Itoh page 27) at a minimal as the mean particle size is an perceived range which is overlapped by Itoh and as such a *prima facie* case of obviousness exists (See MPEP 2144.05). The disclose of 15 microns as the average particle size meets the requirements of claim 1.

Regarding claim 4, it would be inherent that when a particle is compressed under stresses that the apparent density (compressed) would increase in kind. Given similar properties of the HA (particle size, chemical formula) it would exhibit a similar density

under compression. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)

Regarding claim 9, while Pontier does not expressly teach the claimed compressibility profile, it would be inherent that HA of similar properties to the instant claimed invention (particle size and chemical formula) would exhibit the same compressibility profile absent evidence to the contrary. See MPEP 2144.05.

Regarding claim 10, it would be obvious/inherent that since water is the universal solvent that HA will dissolve in it given a modification of the temperature to speed up or slow down the rate of dissolve. See MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 6 July 2009 (hereinafter "Remarks") have been fully considered but they are not persuasive.

Regarding applicant's argument that Pontier does not disclose that 90% of the particles are below 260 microns and 10% above 10 microns, as shown where the particle size being 150 microns is disclosed (see page 253, left hand column), this number could easily be arrived at by meeting the instantly required limitations. As such, given the addition of the obviousness rejection, it is unclear how Pontier does not make the current claim obvious absent an unexpected result. Furthermore, with 185 falling in that average diameter which applicant instantly claims it could easily be construed that indeed Pontier meets the required limitations of claim 1.

Regarding the arguments concerning Itoh; The 103 rejection of claim 2 however has been removed as this argument was indeed convincing, see Remarks at 4. However, the argument that claim 1 (and dependencies thereon excluding claim 2), Itoh provides a similar basis as that already relied upon for Pontier. Namely the fact that a distribution of 90% at 10 microns and 10% at 210 microns will arrive at the 15 micron average and as such would meet the instant claim absent an unexpected result.

Conclusion

Claims 1-4 & 5-11 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard M. Rump whose telephone number is (571) 270-5848. The examiner can normally be reached on Monday through Friday 7:00 AM-4:30 PM (-5 GMT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571)272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. M. R./
Examiner, Art Unit 1793

/Stuart Hendrickson/
Primary Examiner, Art Unit 1793